



10 ADMINISTRATION

Effective: 6/1/96

10.44 CLIA and OSHA Requirements Pertaining to Blood Tests

POLICY: Local WIC agencies must comply with the Clinical Laboratory Improvement Act of 1988 (CLIA) and the Occupational Health and Safety Administration (OSHA) Regulation - Occupational Exposure to Bloodborne Pathogens 29 CFR 1910.30 (1992).

BACKGROUND:

CLIA requires laboratories to obtain a certificate from the Health Care Financing Administration. Because the blood tests performed by WIC (i.e., spun microhematocrit and hemoglobin using HemoCues) are "waived" tests, a Certificate of Waiver is required. However, if the agency performs other laboratory tests (waived, moderately complex, or highly complex), the WIC project should be covered by that certificate, with fees prorated as appropriate.

The OSHA Bloodborne Pathogens Standard requires agencies to have a written exposure control plan that includes an exposure determination of who is occupationally exposed to blood; methods of compliance including engineering controls such as sharps containers, work practices, personal protective equipment, such as gloves and housekeeping; the provision of Hepatitis B vaccination and post-exposure follow-up of exposure incidents; training of all affected personnel on an annual basis; appropriate biohazard labeling; and appropriate recordkeeping including the recording of injuries and illnesses on the OSHA 200 log.

PROCEDURE:

A. CLIA CERTIFICATE

1. New WIC projects must do one of the following:
 - a) obtain a Certificate of Waiver by requesting an application from the Clinical Lab Unit in the Bureau of Quality Compliance in the Wisconsin Division of Health at 608/266-5765
 - b) if the agency already has a Certificate, assure that WIC is covered (e.g, included in policies/procedures pertaining to lab testing)
2. Agencies with Certificates will receive renewal materials from HCFA every two years.
3. Local agencies/projects are responsible for paying the fee for the Certificate. If the Certificate covers more than one program doing testing, the fee should be prorated for WIC blood tests.



4. If you have questions pertaining to requirements and/or the process, contact the Clinical Lab Unit at 608/266-5765.
5. For projects that draw blood for blood lead testing, the actual blood lead test, performed at the State Laboratory of Hygiene or other laboratory, is a high complexity test. But, since WIC may draw blood but not conduct the actual test, this does not affect the waived status that WIC has by performing only finger-puncture microhematocrit tests and hemoglobin tests analyzed by the HemoCue.

B. OSHA BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

1. Complete and/or update and retain a current plan on file.
 - a) If the WIC Project is in an agency that performs additional blood tests (e.g., a health department), WIC should be covered by the agency plan.
 - b) If the WIC Project is the only program in the agency that performs blood testing, a sample plan (in which to fill in required information) is available, including on diskette, from the Section of Occupational Health in the Wisconsin Division of Health at 608/266-9383.
2. If you have questions pertaining to requirements and/or the process, contact the Section of Occupational Health at 608/266-9383.

NOTES:

There is an OSHA directive that pertains to tuberculosis. This directive, however, does not apply to WIC projects because WIC is not residential, does not perform high risk procedures, is not generally hospital based, and does not treat known or suspect TB patients. Therefore, it is not recommended that staff obtain a vaccine.